REMARKS

All claims have been renumbered in accordance with the Examiner's suggestion. Claims 1-18 have been cancelled. Claims 19-32 are currently pending. Claims 20, 21, and 24-32 have been withdrawn. Claims 27-32 have been amended. Claims 19, 22, and 23 are now presented for the Examiner's review and consideration. Applicants believe that the claim amendments and the accompanying remarks, presented herein, serve to clarify the present invention and are independent of patentability.

No new matter has been added by the amendments to claims 27-32 made herein. These claims have been amended only to correct dependencies in light of the claim renumbering.

The paragraphs of the specification noted in this Response are referenced according to the paragraph numbering in the published application, U.S. 2005/0090512 A1.

Related Application

In accordance with the Examiner's request for a complete list of all co-pending and related applications, Applicants submit the following:

U.S. Patent Application Publication 2004/0120985 A1, published on June 24, 2004 (filed on September 17, 2003) is the only related, co-pending application sharing a common inventor, Kurt-Reiner Geiss, with the instant application. This related application is drawn to a food product, containing phosphatidyl serine, for increasing cognitive functional capacity.

Rejections under 35 U.S.C. §112, second paragraph

Claims 19, 22, and 23 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter applicant regards as the invention.

The Examiner asserts that in claim 19 the phrases "including the raised serum prolactin levels are reduced and are increasingly coupled to the human central nervous system" and "including neurotransmitters, dopamine, epinephrine, norepinephrine, and serotonin, which are substantially unaffected" render the claims indefinite, because it is unclear whether or not claim limitations are intended.

Applicants respectfully disagree with the Examiner and assert that the limitations placed on the claim by these phrases are clear from reading the claim. First, the claim recites "human central nervous controls" and not "human central nervous system" as indicated by the Examiner. During the resting period the peripheral controls (of the human) are reduced and increasingly coupled to the central nervous controls (of the human). Prolactin is considered part of the peripheral controls, and thus is raised during extreme physical stress and reduced during the rest period. The neurotransmitters, dopamine, epinephrine, norepinephrine, and serotonin are part of the central nervous controls and are unaffected by the consumption of the L-theanine. In the specification, paragraphs **[0022]-[0039]**, in particular **[0026]-[0036]**, discuss the parameters measured to determine if and how L-theanine effects bodily functions, including the measurement of peripheral reactions, hormonal regulation, and central nervous control. Paragraph **[0039]** discusses the relationship between prolactin and central nervous system hormones. Paragraph **[0046]** discloses that, while drinks containing L-theanine affected

prolactin values, no differences were detected in the values of catecholamines, serotonin, and cortisol. Paragraph **[0051]** discusses the switch points between central electrical brain activity and the peripheral hormonal control and regulating system. Furthermore, these points were clarified in the Declaration of Dr. Weiss, filed on April 13, 2007, which discusses that regeneration and recovery from extreme physical stressing was found to be due to a coupling between the central nervous system and the peripheral endocrine system influenced by L-theanine (paragraphs 12 and 13). Thus, one of ordinary skill in the art, interpreting the claims in light of the specification, would understand that the limitation of these phrases in claim 19 indicates the physiological changes that occur during the rest period that accelerate recovery of the human from the extreme physical stress to complete regeneration.

The Examiner further asserts that, in claim 19, the phrase "extreme physical stress" is indefinite, because the metes and bounds of "extreme" cannot be precisely determined.

Applicants respectfully disagree with the Examiner's assertion. The phrase "extreme physical stress" refers to the stress experienced by a person at the maximum level of an exercise stress test. A stress test is used to evaluate heart function and requires that a patient exercises on a treadmill or stationary bicycle while his or her heart rate, breathing, blood pressure, electrocardiogram (ECG), and feeling of well being are monitored. *See* Dinsmoor, R.S. "Stress Test", from the Gale Encyclopedia of Medicine, published December 2002, by the Gale Group, accessed online on May 21, 2008; copy attached. The patient begins riding a stationary bicycle and gradually, the intensity is increased. For example, the resistance or "drag" on the bicycle is gradually increased. The patient continues exercising at increasing intensity until he or she reaches his or her target heart rate (generally set at a minimum of 85% of the maximal predicted

heart rate based on the patient's age) or experiences severe fatigue, dizziness, or chest pain. *See* Dinsmoor, *supra*. In other words, this technique requires the patient to exercise until exhaustion. *See* Feraco et al. *Archives of Gerontology and Geriatr*ics 23(3):293-298 1996; abstract attached. Clearly, a patient exercised to exhaustion experiences extreme physical stress. This type of "exercise" or "stress" test was common practice at the time of the invention, and thus, one of ordinary skill in the art would be familiar with this test, methods for carrying it out, and evaluation of the results. It is evident in the specification that the phrase "extreme physical stress" refers to the stress experienced by the study participants at the culmination of a bicycle stress test. For example, extreme physical stress is referred to throughout the instant specification. *See* paragraphs **[0010]** and **[0018]**. The investigation model used by the inventors is based on the production of physical stress by means of almost maximum bicycle ergometry. *See* paragraph **[0038]**. The bicycle ergometry is effected as a multi-stage test with increases up to near maximum functional capacity. *See* paragraph **[0041]**. The study participants subjected to the test experienced a rise in electrical performance (measured by EEG) due to physical near maximum stress. *See* paragraph **[0045]**. Accordingly, Applicants respectfully submit that the metes and bounds of the term "extreme" would be recognized by those having ordinary skill in the art.

The Examiner additionally asserts that, in claim 19, the phrase "peripheral controls" is indefinite, because, although it appears that applicants intend to include serum prolactin levels and neurotransmitters among the peripheral controls, the metes and bounds of "peripheral controls" can not be precisely determined.

Applicants respectfully disagree with the Examiner's assertion. The claim indicates that the peripheral controls are coupled to the central nervous controls; "…the peripheral controls of the human including the raised serum prolactin levels are reduced and are increasingly coupled to the human central nervous controls…" emphasis added by Applicants. The claim also indicates that prolactin is part of the peripheral controls and the neurotransmitters part of the central nervous controls. Thus, neurotransmitters are not considered part of the peripheral controls as indicated by the Examiner.

First, one of skill in the art would know the distinctions between the central and peripheral nervous systems; *i.e.* "peripheral" refers to the system outside of the brain and spinal cord. One of skill in the art would also know that neurotransmitters, such as dopamine, epinephrine, norepinephrine, and serotonin, are associated with the central nervous system and that hormones, such as prolactin, cortisol, and endorphins, are associated with the peripheral nervous system. Furthermore, the role of neurotransmitter release in the regulation of the hormonal response to exercise was widely studied at the time of the invention and these studies often combined central and peripheral data. For example, Piacentini et al. studied the effect of a drug (bupropion) on neurotransmitter (including dopamine, norepinephrine, and serotonin) and peripheral hormone (including prolactin) levels in exercising rats. *See* Piacentini et al. Journal of Applied Physiology 95:652-656 2003, in particular, the introduction at page 652, the discussion at page 654; and the section entitled "Peripheral Hormone Concentrations as Markers for Central Effects" at page 655. Similar terms and concepts are evident in the specification as filed. For example, paragraph **[0039]** discusses the relationship between prolactin and central neurotransmitters and paragraph **[0051]** discusses the switch points between central electrical

brain activity and the peripheral hormonal control and regulating system. Therefore, Applicants respectfully submit that the metes and bounds of the term "peripheral controls" would be recognized by those having ordinary skill in the art.

Accordingly, in light of the foregoing, Applicants request reconsideration and withdrawal of the rejection of claims 19, 22, and 23 under 35 U.S.C. §112, second paragraph.

Rejections under 35 U.S.C. §112, first paragraph

Claims 19, 22, and 23 were rejected as allegedly failing to comply with the written description requirement.

The Examiner asserts that, in claim 19, the phrase "as evidenced by raised serum prolactin levels" lacks support in the specification as filed. In paragraph **[0025]** of the specification, measurement of the hypohysen hormone prolactin is discussed, but no raised serum prolactin level is recited. Thus, the Examiner asserts that this recitation represents new matter.

Applicants respectfully disagree with the Examiner's assertion.

Paragraph **[0039]** refers to the measurement of prolactin in the serum after stressing, and that after physical stress, prolactin acts as a stress hormone. A patent need not teach, and preferably omits, what is well known in the art. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); MPEP 2164.01. It was known, well before the time of the invention, that prolactin increases in both animals and humans after stress and/or exercise. *See* attached abstracts of Fava et al. *Stress Medicine* 3(3):211-216 1987; Singh et al. *Medicine & Science in Sports & Exercise* 31(4):536-542 1999; and Lima et al. *Hormones and Behavior*

40(4):526-532 2001. Since it was well known, one of skill in the art would realize that a measurement of prolactin levels after exercise would be a measurement for raised levels. Accordingly, it is not necessary for the specification to include an extensive discussion of raised serum prolactin levels. Furthermore, Table 11 of the Declaration, filed on April 13, 2007, shows the raised serum prolactin levels after physical stressing (and after administration of L-theanine). Thus, Applicants respectfully submit that the recitation of "raised serum prolactin levels" does not constitute new matter.

The Examiner asserts that, in claim 19, the phrase "resting the human" lacks support in the specification as filed. Paragraph **[0027]** of the specification, notes a recovery phase, but no "resting" is recited. Thus, the Examiner asserts that this recitation represents new matter.

Applicants respectfully disagree with the Examiner's assertion.

Mere rephrasing of a passage (in the specification) does not constitute new matter. *See* MPEP 2163.07 I. Paragraph **[0042]** discusses the introduction of a recovery phase after administration of the L-theanine. While the specification does not explicitly recite "resting the human", it recites that the human recovers by lying in a separate, peaceful, darkened room. One reading the specification would understand that a person "lying in a separate, peaceful, darkened room" is resting. Furthermore, known protocols for the stress test indicate that after the test patients should rest until blood pressure and heart rate return to normal. *See* Dinsmoor, *supra*. Thus, Applicants respectfully submit that the recitation of "resting the human" does not constitute new matter.

The Examiner asserts that, in claim 19, the phrase "peripheral controls" lacks support in the specification as filed. In paragraph **[0035]** of the specification, peripheral hormonal control

and regulating system are discussed, but the recitation "peripheral controls" is broader. Thus, the Examiner asserts that this recitation represents new matter.

Applicants respectfully disagree with the Examiner's assertion.

As mentioned above, one of ordinary skill in the art would be familiar with both the concept of neurotransmitter release in the regulation of the hormonal response to exercise and with the terms "central" and "peripheral" used in reference to the data regarding the neurotransmitters and to the data regarding the hormonal response, respectively. Furthermore, it is evident in the specification the term "peripheral controls" refers to hormonal regulation. For example, paragraph **[0051]** discusses the switch points between central electrical brain activity and the peripheral hormonal control and regulating system. Thus, Applicants respectfully submit that the recitation of "peripheral controls" does not constitute new matter.

The Examiner asserts that, in claim 19, the phrase "neurotransmitters dopamine, epinephrine, norepinephrine, and serotonin, which are substantially unaffected" lacks support in the specification as filed. In paragraph **[0025]** of the specification, the recited hormones are discussed, but their being substantially unaffected is absent. Thus, the Examiner asserts that this recitation represents new matter.

Applicants respectfully disagree with the Examiner's assertion.

Mere rephrasing of a passage (in the specification) does not constitute new matter. *See* MPEP 2163.07 I. Paragraph **[0046]** notes that no differences were observed in the levels of catecholamines (*i.e.* dopamine, epinephrine, norepinephrine) and serotonin after administration of drinks containing L-theanine. Thus, one would understand that the levels of these substances were substantially unaffected, in the test subjects, after consumption of the drinks containing L-

theanine. Thus, Applicants respectfully submit that the recitation of "neurotransmitters dopamine, epinephrine, norepinephrine, and serotonin, which are substantially unaffected" does not constitute new matter.

Accordingly, in light of the foregoing, Applicants request reconsideration and withdrawal of the rejection of claims 19, 22, and 23 under 35 U.S.C. §112, first paragraph (written description).

Claims 19, 22, and 23 were rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement, and, as containing subject matter that allegedly was not described in the specification in such a way as to enable one skilled in the art to practice the invention.

The Examiner states that claim 19 recites "treating extreme physical stress" and "to complete regeneration" and asserts that there is insufficient written description for these claim limitations in the disclosure.

The Examiner asserts that, according to Stedman's Medical Dictionary, the term "stress" is *inter alia* any physical or psychological stimulus that can produce mental tension or physiological reactions that may lead to illness. Further, according to Stedman's Medical Dictionary, the term "regeneration" is any regrowth of lost or destroyed parts or organs.

The Examiner asserts that Applicants have used terms that are outside the generally recognized definitions that would reasonably be accepted by one skilled in the medical community. Although Applicants may be their own lexicographers, a description of the claimed invention with all of its limitations through words, structures, figures, and/or diagrams that fully

set forth the claimed invention is required. Therefore, the Examiner concludes that it is not clear if Applicants were in possession of the full scope of the claimed methods at the time that the invention was made.

Applicants respectfully disagree with the Examiner's assertions and respectfully submit that the Examiner's limitation of the meaning of the terms "stress" and "regeneration" to the definitions recited in one dictionary (Stedman's Medical Dictionary, 1995) is improper. During patent examination, the pending claims must be given their broadest reasonable interpretation consistent with the specification as it would be interpreted by one of ordinary skill in the art. *In re Am. Acad. of Sci. Tech. Ctr.,* 367 F.3d 1359, 1364 [,70 USPQ2d 1827] (Fed. Cir. 2004); MPEP 2111.

The claims, as presented herein, recite "treating extreme physical stress." The instant specification discusses the production of physical stress in humans by means of bicycle ergometry and further discusses measurement of the levels of stress hormones and heart rate as indicators of the stress produced. *See* paragraphs **[0037]-[0047]**. As discussed above, the phrase "extreme physical stress" refers to the stress experienced by a person at the maximum level of an exercise stress test; *i.e.* the person's maximum functional capacity or point of exhaustion. See paragraph **[0041]**. Thus, one of ordinary skill in the art would clearly understand, from the specification, that the physical stress referred to in the claims is stress brought about by physical activity or exercise and the extreme physical stress occurs at the maximum level of this physical activity or exercise.

Furthermore, there are many recognized definitions for the term "stress" that coincide with the term as used in the instant specification. For example, The American Heritage Science

Dictionary (2002) defines stress as "a physiological reaction by an organism to an uncomfortable or unfamiliar physical or psychological stimulus. Biological changes results from stimulation of the sympathetic nervous system, including a heightened state of alertness, anxiety, increased heart rate, and sweating." *See*, page 5 of the attached definition of "stress", as obtained on the web site *dictionary.com*.

Accordingly, Applicants respectfully submit that the term "stress" is clearly described in the instant specification and further, is used in accordance with art-recognized definitions of the term.

Claim 19 also recites the term "regeneration." The instant specification refers to "regeneration after stressing", "relaxing or recovering after stress", and "switching from activity to recovery." *See* the abstract and paragraphs **[0038]**, **[0042]**, **[0049]**, and **[0056]**. Thus, it is clear from the specification that regeneration refers to recovery from extreme physical stress. Furthermore, the regrowth of destroyed or lost parts or organs is not mentioned anywhere in the specification. Thus, since the claims are interpreted in light of the specification, and regeneration is not discussed as regrowth in the specification, one of ordinary skill in the art would clearly not interpret the recitation of "regeneration" in the claims to refer to regrowth of lost parts or organs.

In addition, there are recognized definitions for the term "regeneration" that coincide with the term as used in the instant specification. For example, The American Heritage Dictionary (2006) defines regeneration as "the act or process of regenerating or the state of being regenerated." *See*, page 1 of the attached definition of "regeneration", as obtained on the web site *dictionary.com*.

Accordingly, Applicants respectfully submit that the term "regeneration" is clearly described in the instant specification and further, is used in accordance with art-recognized definitions of the term.

Thus, Applicants respectfully submit that they were in possession of the full scope of the claimed methods at the time that the invention was made, and further, that one of ordinary skill in the art could practice the claimed methods after review of the instant specification.

Accordingly, in light of the foregoing, Applicants request reconsideration and withdrawal of the rejection of claims 19, 22, and 23 under 35 U.S.C. §112, first paragraph (written description and enablement).

Conclusion

In light of the foregoing amendments and remarks, this application is now in condition for allowance, and early action is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

A fee of $180 is believed due for the Information Disclosure Statement, which is submitted concurrently herewith. Please charge any other required fee (or credit overpayments) to the Deposit Account of the undersigned, Account No. 500601 (Docket No. 7390-X03-020).

Respectfully submitted,

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